K131959

MAR - 7 2014

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, HEINE Optotechnik GmbH & Co. KG herewith submits a Summary of Safety and Effectiveness.

Submitter Information:
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Germany
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Owner/Operator Number: 9003020

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Date Prepared: February, 2nd 2014

Device(s) Identification:
Device Trade Name: HEINE mini 3000® Ophthalmoscope
Common Name: Ophthalmoscope

Classification of the device:
Device Classification Name: Ophthalmoscope
Product Code: HLJ
Device Classification No.: Part 886.1570
Panel: Ophthalmic Devices (86)
Regulatory Status: Class II

Device Description:
The HEINE mini 3000® Ophthalmoscope is a battery powered hand-held device to provide illumination and viewing optics in order to examine the media and the retina of a patient's eye. It consists of an instrument head and a battery handle that can be screwed onto the instrument head. The ophthalmoscope can be either operated by replaceable AA batteries or a rechargeable option in combination with the HEINE mini NT® charger.

Intended Use:
The HEINE mini 3000® Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intend to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.

Predicate Device:

Device Trade Name:	HEINE mini 3000® LED
Applicant:	HEINE Optotechnik GmbH & Co. KG
510(k) No.:	K123587

The HEINE mini 3000® Ophthalmoscope is considered substantial equivalent to the HEINE mini 3000® LED Ophthalmoscope (K123587).
There is no significant difference in intended use or technology.

	HEINE mini3000® Ophthalmoscope	HEINE mini3000® LED Ophthalmoscope	Assessment
Intended Use	The HEINE mini3000® Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	The HEINE mini3000® LED Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.	Same
Type	Monocular	Monocular	Same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye.	Used to examine the retina by an examiner in a specific distance to the eye.	Same
Illumination type	Halogen filament bulb	LED	Different
Exposure parameters	Emission of 2.5 V halogen bulb	Emission of a white LED	Different[3]
Light output[1]	315 lux	542 lux	Different[3]
Filter	Red free filter	Red free filter	Same
Service life of illuminant	approx. 45 hours	unlimited	Different
Diopters	+ 20D to –20D	+ 20D to –20D	Same
Lens power viewing optics	Diopter of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1, 0, 1, 2, 3, 4, 6, 8, 10, 15, 20	Diopter of used lens in steps: -20, -15, -10, -8, -6, -4,-3, -2, -1, 0, 1, 2, 3, 4, 6, 8, 10, 15, 20	Same
Light apertures[1]	small circle D = 13,8 mm large circle D = 27,3 mm semicircle medium circle with reticle D = 23,1 mm	small circle D = 13,8 mm large circle D = 27,3 mm semicircle medium circle with reticle D = 23,1 mm	Same
Method of operation	Used to examine the retina by an examiner in a specific distance to the eye	Used to examine the retina by an examiner in a specific distance to the eye	Same
Correction lens adjustable with left / right hand	Yes	Yes	Same
Supply voltage	2.5 V	2.5 V	Same
Power sources[2]	2 alkaline cells (size LR6/AA) / HEINE mini 2Z rechargeable battery	2 alkaline cells (size LR6/AA) / HEINE mini 2Z rechargeable battery	Same
Brightness controls	none	none	Same
Maximum temperature of parts of the device held by the operator or accessible to the patient	Complies with IEC 60601-1 for temperatures of external surfaces and controls[4]	Complies with IEC 60601-1 for temperatures of external surfaces and controls[4]	Equivalent
Flammability of materials	Low probability. All measures have been taken to use self-extinguishing materials. The system is illuminated using a xhl lamp and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Low probability. All measures have been taken to use self-extinguishing materials. The system is illuminated using a 3W LED lamp and all materials used in the vicinity are specially designed to safely operate in high temperature environments.	Equivalent

Note 1: Measurements taken 200 mm from output (direct ophthalmoscopes), large circle aperture
Note 2: All power sources comply with the relevant standard of IEC 60601-1 and IEC 60601-1-2.

Note 3: The XHL bulb is considered to be acceptable because of the following aspects:

a) The emission spectrum and the emission intensity of LED bulbs remains constant with respect to fluctuations of the power supply and are constant over its whole lifetime. If the battery voltage decreases, the LED color temperature does not change, which is the case with halogen.
b) The color reproduction of the HEINE mini3000® LED Ophthalmoscope (color temperature 4000K) is comparable to that of a halogen bulb.
c) XHL has lower light output than LED. The maximum exposure time is specified in the instructions for use.

Note 4: Chapter 17 of this submission contains the corresponding test report No. E256178-A18-CB-1. Please refer to clause 42 of test report E256178-A18-CB-1 for further details.

Summary of Non-Clinical Performance Testing:
The HEINE mini 3000® Ophthalmoscope is tested according to the "Ophthalmoscope Guidance" in respect to optical radiation hazard with ophthalmoscopes (ISO 10942). Additionally testing in accordance with applicable requirements of ISO 15004-2 "Ophthalmic instruments – Fundamental requirements and test methods" has been performed.

Conclusion:
HEINE Optotechnik believes that the HEINE mini 3000® Ophthalmoscope is substantially equivalent to the currently legally marketed devices. It does not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.

Summary Report

The HEINE mini 3000® Ophthalmoscope is tested according to the "Ophthalmoscope Guidance" in respect to optical radiation hazard with ophthalmoscopes (DIN EN ISO 10942:2007). Additionally testing in accordance with applicable requirements of ISO DIN EN 15004-2:2007 "Ophthalmic instruments – Fundamental requirements and test methods" has been performed.

The bench test results are described in the following reports:

Standard	Test Identification No.	Document No.
ISO 15004-2	ISO 15004-2_mini3000XHLOphth NR. L-56_13 Heine Mini 3000 (Risk group classification)	18a 18b
ISO 10942	ISO 10942_mini3000XHL_Ophth	18c

Bench Test HEINE mini3000® Ophthalmoscope
According to EN ISO 15004-2:2007

Based on Test Report NR. L-56_13 Heine Mini 3000
Issued by Seibersdorf Laboratories
Date: 11.06.2013 (11th of June 2013)

Table 3 has been used for this report because it represents the worst case of intended use of the device and the results are calculated according to the methods of DIN EN ISO 15004-2:2007.

The instructions for use contain the maximum time at maximum intensity up to 47 seconds (worst case) as specified in the test report.

Bench Test Table 3:

Parameter	Test specification	Wavelength	Limit Group 2	Test result	Verdict
Weighted corneal and lenticular UV, *ES*-CL, *HS*-CL	The corneal radiant exposure shall be evaluated by averaging highest localized radiation power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).	250 - 400	3 mJ cm^{-2}	0,008 µW cm^{-2}	PASS
Unweighted corneal and lenticular UV, *E*UV-CL, *H*UV-CL	The corneal radiant exposure shall be evaluated by averaging highest localized radiation power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).	360 - 400	1 J cm^{-2} (t < 1000 s)	0,019 µW cm^{-2}	PASS
Unweighted corneal and lenticular infrared, *E*IR-CL	The corneal irradiance shall be evaluated by averaging the highest localized radiation power incident upon a circular area at the corneal plane with a diameter of 1 mm ($7{,}9 \times 10^{-3}$ cm^2).	770 – 2500	100 mW cm^{-2}	1,65 µW cm^{-2}	PASS
Unweighted anterior segment visible and infrared, *E*VIR-AS, *H*VIR-AS	The unweighted anterior segment irradiance shall be evaluated by averaging the highest localized radiation power incident upon a circular area at the corneal plane with a diameter of 0,5 mm ($2{,}0 \times 10^{-3}$ cm^2).	380 – 1200	20 W cm^{-2}	Not applicable	PASS
Weighted retinal radiance, *Li*, A-R	Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,011 rad. However, if the instrument is designed to be used with an eye that is immobilized, a field-of-view of 0,001 75 rad shall be used instead of the 0,011 rad field-of-view.	305 - 700	100 J cm^{-2} sr^{-1}	11 mrad: 1216 mW cm^{-2} sr^{-1} 1,75 mrad: 2124 mW cm^{-2} sr^{-1}	PASS

Parameter	Test specification	Wavelength	Limit Group 2	Test result	Verdict
Weighted retinal visible and infrared thermal radiance, *L*VIR-R	In the expression for the limit value, under normal intended use conditions, *dr*, expressed in millimetres, is the minimum retinal image diameter of the source based on the standard eye (see Annex D for instructions on the way to determine the value of *dr*). If the calculated value of *dr* is greater than 1,7 mm, the value 1,7 mm shall be used for *dr*. If the calculated value of *dr* is less than 0,03 mm, the value of 0,03 mm shall be used for *dr*. Measurements of radiance shall be the radiant power detectable through a 7 mm diameter aperture at the cornea and shall be averaged over a right circular cone field-of-view of 0,001 75 rad.	380 – 1400	29,4*) $W\,cm^{-2}\,sr^{-1}$	1,75 mrad: 19,9 $W\,cm^{-2}\,sr^{-1}$	PASS

*) = 20 mrad (worst case assumption)

Summary:

The HEINE mini3000® Ophthalmoscope fulfills the requirements according to EN ISO 15004-2:2007, group 2.

The HEINE mini3000® Ophthalmoscope is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

HEINE Optotechnik GmbH & Co. KG
c/o Ms. Belinda Labourdette
Executive Assistant
10 Innovation Way
Dover, NH 03820

Re: K131959
Trade/Device Name: HEINE Mini 3000® Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLJ
Dated: January 28, 2014
Received: February 4, 2014

Dear Ms. Labourdette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K131959

Device Name: HEINE mini 3000® Ophthalmoscope

Indications For Use:
The HEINE mini 3000® Ophthalmoscope is a battery powered hand-held device for medical professionals, containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, vitreous) and the retina of the eye.

Prescription Use___X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marsha L. Burke Nicholas -S

Digitally signed by Marsha L. Burke Nicholas -S
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Date: 2014.03.04 13:53:46 -05'00'